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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,135	12/11/2003	Charles Joel Arntzen	P00245US17	8272

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801 GRAND AVENUE
SUITE 3200
DES MOINES, IA 50309-2721

EXAMINER	
WORLEY, CATHY KINGDON	
ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
12/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,135	ARNTZEN ET AL.	
	Examiner	Art Unit	
	Cathy K. Worley	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 15, and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Oct. 31, 2007, has been entered.

2. New claims 15 and 16 are directed to the elected invention. Claims 1-16 are pending. Claims 11-14 are withdrawn. Claims 1-10, 15, and 16 are examined in the present office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 16 is drawn to a method of producing an immunogenic comprising the step of transforming a plant wherein the plant is transformed without wounding. The additional limitation of transforming the plant without wounding is NEW MATTER. The instant specification does not provide support for transformation of a plant specifically without wounding.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-10 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 5,792,935, issued on Aug. 11, 1998, for the reasons of record stated in the previous Office Actions mailed on Jan. 18, 2007 and on Sept. 17, 2007. The Applicant's

arguments in the response filed on Oct. 31, 2007, were fully considered but were not found to be persuasive.

The instant claims are drawn to a method of producing an immunogenic composition, wherein said method comprises the steps of transforming a plant with a nucleic acid encoding a recombinant viral immunogen, and producing from said plants said composition. New claim 15 is specifically directed to a method wherein the plant is not a banana plant.

Claims 14 of U.S. Patent No. 5,792,935 (herein after the '935 patent) is drawn to a method for producing a transgenic Musa plant expressing a pharmaceutical protein, including the hepatitis B surface antigen and the Norwalk virus capsid protein.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1 and 3 of the instant application encompasses methods of producing any mammalian viral immunogen in any plant, or of producing an immunogen from any transmissible gastroenteritis virus in any plant; therefore, claim 14 of the '935 patent encompasses a species of the genus encompassed by the instant claims (ie. hepatitis B is one mammalian viral immunogen and Norwalk capsid protein is an immunogen from one transmissible gastroenteritis virus; and a Musa plant is one kind of plant). Because a species anticipates the genus, claim 14 of the '935 patent anticipates claims 1 and 3 of the instant application.

The remaining limitations in the instant claims 2 and 4-10 that do not appear in the issued patent are obvious in view of the prior art.

The Applicant argues that the prior art does not teach each element of the claim under consideration (see paragraph bridging pages 23-24 of the response), and that, specifically, it does not teach expressing the recombinant viral immunogen at a level that elicits an immunogenic response upon oral administration such that the animal is protected against viral challenge (see first paragraph on page 7 of the response).

This is not persuasive, however, because the '935 patent teaches the use of the rice actin 1 promoter and the use of the cauliflower mosaic virus 35S promoter which are both known in the art to drive constitutively high levels of expression. Furthermore the instant claims do not include any specific concentration, required, nor do they include any strength of immune response required; therefore, even if a weak immune response is achieved, it would satisfy the instant claims. The method step of selecting those plants that elicit an immune response is an obvious method step in view of the prior art.

The Applicant further argues that the '935 patent does not provide a reasonable expectation of success (see paragraph bridging pages 7-8 of the response). The Applicant states that high levels of plant proteins may have been achievable, but there is no expectation of success that a viral mammalian protein would be capable of expression in a plant since the viral immunogen would

normally only be expected to express in a mammal due to viral tropism (see top of page 8). This is not persuasive, because the plant taught in the '935 patent was transformed with a construct comprising a promoter that functions in plants, therefore, there is no need for the virus to be infective, because the construct is incorporated into the genome of the plant, and the initiation of transcription relies on a promoter that functions in plants. Therefore, there is an expectation of success in producing high levels of recombinant protein utilizing this method.

In addition, the Applicant argues that there would be no expectation that the protein would be properly folded such that it could elicit an immune response and that the '935 patent does not provide any data indicating that the hepatitis B surface antigen (HBsAG) can actually be expressed in banana plants (see page 8). This is not persuasive, however, because the '935 patent teaches that the HBsAG produced in the transgenic banana plant was immuno-reactive and detectable by the Auszyme monoclonal kit which binds to HBsAG derived from human serum (see column 11, lines 40-45). This demonstrates that the HBsAG was produced in the banana plants and was folded correctly.

Lastly, the Applicant argues that there would be no expectation of success in eliciting an immunogenic response or providing protection from viral challenge (see page 8). This is not persuasive, however, because selection of host plants with high levels of expression was well known in the art, and the ability to elicit an immune response is an intrinsic property of the hepatitis B surface antigen. Once an

immune response has been elicited in a subject, that subject would be protected against a viral challenge.

New claim 15, specifically recites the limitation that the plant is not a banana plant. This limitation does not overcome the obviousness of the claim over the '935 patent, because it would have been obvious to one of ordinary skill in the art that the construct taught in the '935 patent could be transformed into other species of plants, especially given that the promoters taught in the '935 patent were the rice actin 1 promoter and the cauliflower mosaic virus 35S promoter which are known to function in other species of plants.

5. Claim 16 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 5,792,935, issued on Aug. 11, 1998 in view of Feldmann (The Plant Journal (1991) Vol.1, pp. 71-82).

Claim 16 is directed to a method of producing an immunogenic composition, wherein said method comprises the steps of transforming a plant with a nucleic acid encoding a recombinant viral immunogen, and producing from said plants said composition; wherein the method of transforming the plant does not comprise wounding the plant.

Claims 14 of U.S. Patent No. 5,792,935 (herein after the '935 patent) is drawn to a method for producing a transgenic Musa plant expressing a pharmaceutical protein, including the hepatitis B surface antigen and the Norwalk virus capsid

protein (see double-patenting rejection, above). Feldmann teaches a method of transformation that does not involve wounding the plant (see paragraph bridging left and right columns on page 80). At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to utilize any proven method of transformation, including the method taught by Feldmann et al; therefore, the instant claim 16 is obvious over claim 14 of US Patent No. 5,792,935 in view of Feldmann.

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cathy K. Worley
Patent Examiner
Art Unit 1638

CKW